IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JOHN J. "GUS" HOEFLING and MARGARET HOEFLING, his wife, *Plaintiffs*, v. U.S. SMOKELESS TOBACCO CO., LLC; and PINKERTON TOBACCO CO., LP, *Defendants*	CIVIL ACTION NO. 19-3847

PAPPERT, J. **December 21, 2021**

MEMORANDUM

John J. "Gus" Hoefling used smokeless tobacco for more than thirty years. He claims Red Man, a loose leaf chewing tobacco manufactured by Pinkerton Tobacco Co. LP, and Skoal, a moist snuff manufactured by U.S. Smokeless Tobacco Company, caused the squamous cell carcinoma on his left tonsil. He believes the cancer is the result of Defendants' defectively designed products and their failure to adequately warn him about known risks associated with Red Man and Skoal. His wife, Margaret "Maggie" Hoefling, asserts a claim for loss of consortium.

Pinkerton and U.S. Smokeless move to exclude the medical causation opinions of Drs. Paul Busse, Bruce Chabner and Scott Tomar. Dr. Tomar offers an opinion on general causation only, while Drs. Busse and Chabner also claim that Defendants' products specifically caused Hoefling's tonsil cancer. Pinkerton and U.S. Smokeless acknowledge the experts' qualifications but argue their opinions are not reliable and do not fit the facts of this case. *See* (ECF 71, 74 and 76). Because Hoefling needs their opinions to prove that Pinkerton or U.S. Smokeless caused his tonsil cancer, Defendants have also filed motions for summary judgment. (ECF 73 and 75.) After a

thorough review of the record and oral argument, the Court grants Defendants' motions to exclude all three causation experts' opinions. Absent those opinions, no reasonable jury could return a verdict in the Hoeflings' favor so the Court also grants Pinkerton's and U.S. Smokeless's summary judgment motions. Even if the Court allowed the experts' opinions, it would still enter judgment for the Defendants because the Hoeflings could not prove causation under Pennsylvania law.

I

A

Hoefling first tried Red Man in 1973, when he was thirty-eight or thirty-nine. (U.S. Smokeless SOMF, ECF 75-2, ¶ 8.) Red Man is a type of chewing tobacco made from chopped, cured loose tobacco leaves. (Pinkerton SOMF, ECF 73-8, ¶ 38.). He used Skoal for the first time in 1976 or 1977. (*Id.* ¶ 15.) Skoal is a type of moist snuff made from finely ground or shredded tobacco leaves that are fermented during the curing process. (*Id.* ¶ 38.) Skoal became Hoefling's "primary tobacco," but he still used Red Man. (*Id.* ¶ 8.) Specifically, he used two to five cans of Skoal and chewed three bags of Red Man each week. (Hoefling Resp. to Pinkerton Interrog. No. 2, ECF 75-7 at 4.) When he began using the products, they bore "no warnings" and Hoefling "had no idea [he] would become addicted." (Hoefling Dep., ECF 75-6, at 317:10–13; 384:4.)

Since 1987, federal law has required smokeless tobacco packages to bear one of three warnings: (1) WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER; (2) WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS; (3) WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES. *See* (*id.*, ¶ 64; U.S. Smokeless SOMF, ¶ 29). Hoefling saw, read and was aware of

warnings on Skoal and Red Man since the warnings' inception. (Pinkerton SOMF, ¶ 65; U.S. Smokeless SOMF, ¶ 30.) Nevertheless, he did not quit until 2011, when he was seventy-seven, after asking the cashier who typically sold him smokeless tobacco at his local gas station not to sell him "any more Red Man." (U.S. Smokeless SOMF, ¶¶ 20–21.) He decided he "was being totally controlled by the product . . . . It was affecting [his] life," he believed "it would start to affect his marriage" and "[i]t was certainly going to affect [his] health." (Hoefling Dep., 364:16–24.)

B

In December 2018, when Hoefling was eighty-six, he was diagnosed with squamous cell carcinoma of the left tonsil. (Pinkerton SOMF, ¶ 18.) He underwent radiation treatment and, in November 2019, imaging showed previous "mild activity" in his left tonsillar region "at background compatible with treated malignancy," with no evidence of recurrence. (*Id.*)

Alcohol, smoking and human papillomavirus ("HPV") infection are acknowledged risk factors for tonsil cancer. (*Id.* ¶ 19.) Hoefling alleges he never consumed alcohol and there is no record evidence to the contrary. *See* (Am. Compl., ECF 13, ¶ 64). In addition to using smokeless tobacco, Hoefling smoked cigarettes in high school at least occasionally. (Pls.' Resp. to Pinkerton SOMF, ECF 85-15, ¶ 13.) His medical records suggest he may have smoked after that, but no witness testimony corroborates those records. (*Id.*)

HPV causes eighty percent of tonsil cancers and seventy percent of cancers occurring in the oropharynx, which is part of the pharynx and behind the oral cavity. (Pinkerton SOMF, ¶ 92; Mundt. Rpt., ECF 76-13 at 5 (presenting anatomical diagram

of throat, mouth and nose).) Crucially, no one knows if Hoefling's tumor was HPV positive; a fine-needle biopsy taken when he was diagnosed had insufficient cellularity to permit a test to rule out HPV as the cause. (*Id.* ¶ 20.) No further biopsy was ordered. (*Id.* ¶ 21.)

C

After Hoefling's diagnosis, he and his wife sued Pinkerton, U.S. Smokeless and others in the Philadelphia County Court of Common Pleas, and U.S. Smokeless removed the case to this Court. (ECF 1.) The Hoeflings then amended their Complaint, leaving U.S. Smokeless and Pinkerton as the only defendants. (ECF 13.) They also voluntarily dismissed Hoefling's fraud and negligent misrepresentation claims (ECF 21 at 12) and stipulated to limit his general negligence claim to theories based on an alleged failure to warn or certain design defects. (ECF 33 at 3.) The Court dismissed the Hoeflings' conspiracy claim without prejudice. (ECF 34.) It then denied U.S. Smokeless's motion seeking to transfer venue to the Middle District of Florida. (ECF 63, 64.) They only claims remaining are for failure to warn and design defect (both in negligence and strict liability) (Counts I–IV) and loss of consortium (Count VIII).

II

To prevail on his product liability claims, Hoefling must prove general and specific causation. *See In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 176 F. Supp. 3d 483, 491 (E.D. Pa. 2016) (*Zoloft III*) (citing *Wells v. SmithKline Beecham Corp.*, 601 F.3d 375, 377–78 (5th Cir. 2010)); *see also Paoli*, 35 F.3d at 752 (explaining plaintiffs must show the product "can cause the types of harm they suffered, and that

the [product] in fact did cause them harm"). General causation addresses whether a product is "capable of causing a particular injury or condition in the general population," and specific causation goes to whether it "caused a particular individual's injury." *Zoloft III*, 176 F. Supp. 3d at 491. Hoefling "must establish general causation before moving to specific causation." *Id.* (noting plaintiff's claim fails absent "predicate proof of general causation").

A

Hoefling "must present admissible expert testimony" to prove causation because this case "involv[es] complex issues of causation not readily apparent to the finder of fact." *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 525 (W.D. Pa. 2003). In *Daubert v. Merrell Dow Pharmaceuticals*, the Supreme Court held that "[f]aced with a proffer of expert scientific testimony . . . the trial judge must determine at the outset . . . whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue." 509 U.S. 579, 592 (1993). In *Kumho Tire Co. v. Carmichael*, the Supreme Court made clear that the Court's *Daubert* gatekeeping function extends beyond scientific testimony to include testimony based on "technical" and "other specialized knowledge." 526 U.S. 137, 141 (1999). The district court acts "as a gatekeeper to ensure that the expert's opinion is based on the methods and procedures of science rather than on subjective belief or unsupported speculation." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 290 (3d Cir. 2012) (internal quotations omitted). *Daubert* "focuses on principles and methodology, not on the conclusions generated by principles and methodology." *In re TMI Litig.*, 193 F.3d 613, 665 (3d Cir. 1999), *amended*, 199 F.3d 158 (3d Cir. 2000).

Thus, a witness with "knowledge, skill, experience, training, or education" to qualify as an expert

> may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. Rule 702 embodies "a trilogy of restrictions on expert testimony: qualification, reliability and fit." *Schneider ex rel. Est. of Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003) (citations omitted). U.S. Smokeless and Pinkerton seek to exclude the general causation opinions of Drs. Busse, Chabner and Tomar and Busse and Chabner's specific causation opinions.[1] Their qualifications are not at issue.[2] U.S. Smokeless and Pinkerton contest only their opinions' reliability and fit.

Daubert's "reliability analysis . . . applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, and the link between the facts and the conclusion." *ZF Meritor*, 696 F.3d at 291 (internal quotations omitted). "Rule 702 grants the district judge the discretionary authority, reviewable for its abuse,

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[1] Dr. Tomar's expert report contains a specific causation opinion. (ECF 70-3 at 5, 7). Plaintiffs subsequently clarified, however, that they seek to have him testify only to general causation. (Pls. Resp. to Pinkerton Mot. to Excl. Tomar Ops., ECF 81 at 1; Pls. Resp. to U.S. Smokeless Mot. to Excl. Med. Caus. Exps., ECF 84 at 5.)

[2] Dr. Busse is a radiation oncologist and associate professor at Harvard Medical School who holds an endowed chair at Massachusetts General Hospital. (Busse Rpt., ECF 71-5 at 1–2.) He has treated nearly 5,000 patients with head and neck cancer. (*Id.* at 1.) Dr. Chabner is a Harvard Medical School professor and clinical director emeritus at the Massachusetts General Hospital Cancer Center. (Chabner Rpt., ECF 71-6 at 2.) He has written and edited a textbook on cancer chemotherapy and biological-response modifiers. (*Id.*) Dr. Tomar is a professor and associate dean at the University of Illinois at Chicago College of Dentistry. (Tomar Rpt., ECF 70-3 at 3.) He has consulted on smokeless tobacco issues for many agencies and organizations and served as a FDA smokeless tobacco expert. (*Id.* at 3–4.)

to determine reliability in light of the particular facts and circumstances of the particular case." *Kumho Tire*, 526 U.S. at 158. An expert's proponents "do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994). When considering whether expert testimony is reliable, relevant factors include:

> (1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put.

U.S. v. Mitchell, 365 F.3d 215, 235 (3d Cir. 2004) (citation omitted). "As long as an expert's scientific testimony rests upon good grounds, based on what is known, it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors' scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies." *Id.* at 244 (citations and internal quotation omitted). "Rule 702 and *Daubert* put their faith in an adversary system designed to expose flawed expertise." *Id.* at 244–45.

The "fit" requirement means "the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact." *Schneider*, 320 F.3d at 404. Fit ". . . goes primarily to relevance. Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591 (citations and internal quotations omitted). "'Fit' is not always obvious, and scientific validity for one

purpose is not necessarily scientific validity for other, unrelated purposes." *Id.*

B

1

Dr. Busse's general causation opinion is not reliable. His expert report summarizes his opinions' basis: (1) The WHO's International Agency for Research on Cancer ("IARC") concluded "[s]mokeless tobacco causes cancers of the oral cavity"; (2) the U.S. Surgeon General determined smokeless tobacco "can cause cancer and a number of non-cancerous oral conditions and can lead to nicotine addiction and dependence"; (3) the American Academy of Otolaryngology ("AAO") and CDC determined "smokeless tobacco products contain cancer causing chemicals," the most harmful of which include tobacco-specific nitrosamines ("TSNAs"); and (4) every "major public health organization," such as the WHO, American Cancer Society and National Cancer Institute, has identified smokeless tobacco as a "cause of oral cancer." (Busse Rpt., ECF 71-5 at 4 (internal quotations omitted).)

The sources Dr. Busse relies on do not support his opinion that smokeless tobacco, including Skoal and Red Man, can in general cause tonsil cancer. This violates *Daubert*'s requirement that his opinion rest upon "good grounds." *Paoli*, 35 F.3d at 742 (quoting *Daubert*, 509 U.S. at 590). The IARC did not conclude smokeless tobacco causes tonsil or oropharyngeal cancer. (Busse Dep., ECF 71-3 at 113:7–23, 115:2–116:16; Chabner Dep., ECF 71-4 at 83:1–20; Tomar Dep., ECF 70-2 at 184:1–185:24). It found a causative link only to oral-cavity, esophageal and pancreatic cancer. (*Id.*) Moreover, the 1986 Surgeon General report pointed to evidence that using snuff can cause cancer, with the "strongest" evidence for oral-cavity cancer. (ECF 71-2, ¶ 2.) But

it did not conclude smokeless tobacco causes oropharyngeal cancer. (*Id.*) In fact, it stated there was "sparse" evidence of any association between "smokeless tobacco use and cancers outside of the oral cavity." (Busse Dep. at 128:15–17.) The tonsil is in the oropharynx, not the oral cavity. Patients are not diagnosed with "head and neck cancer" but rather cancers of more narrowly defined anatomical sites, which have different risks—including the oropharynx or tonsil. *See* (Chabner Dep. at 152:6–22).[3]

In addition to relying on multiple sources that do not justify his view, Dr. Busse ignores other information and research. Causal conclusions require examining "the literature as a whole." *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 449, 461 (E.D. Pa. 2014) (*Zoloft I*) (explaining the "accepted scientific practice" is not for experts to "simply ignor[e] certain studies" but rather explain why they "give[] more weight" to particular studies when forming an opinion). In forming his general causation opinion, Dr. Busse relied on the authorities he cites in his report, case-specific documents like Hoefling's medical records and a 1981 article based on a study of 255 women in North Carolina. (Busse Dep. at 59:1–17; Busse Rpt. at 2; Winn Art., ECF 71-9.) He did not do an "in depth" review of any epidemiological research published after 1981. (Busse Dep. at 55:22–24.) Nor did he independently review the epidemiological research cited by the Surgeon General report or IARC. (*Id.* at 58:20–24.) Dr. Busse did not review the 2016 Wyss study, which Dr. Chabner described as one of the "more complete" articles on smokeless tobacco products and Dr. Tomar

[3] The deposition testimony Plaintiffs highlight from U.S. Smokeless expert Dr. Richmon does not indicate otherwise. (Pls.' Resp. to U.S. Smokeless Mot. to Excl. Med. Caus. Exps., ECF 84 at 11–12.) The testimony is misleading in that the term "oral cancer" is used in a broader sense—as an "umbrella term" encompassing the oral cavity and oropharynx—than it is elsewhere in the record. *See* (Richmon Dep., ECF 84-5 at 18:2–20:15).

characterized as the most "on point" for his work on this case. (*Id.* at 55:3–5; Chabner Dep. at 77:17–20; Tomar Dep. at 188:7–12.) The study pooled data from eleven case-controlled studies of pharyngeal, laryngeal and oral cancers and, importantly, controlled for cigarette smoking—a common "confounder" in studies of smokeless tobacco products—to estimate "associations between smokeless tobacco products and [head and neck cancer], including associations for exclusive use of smokeless tobacco products and associations with specific tumor sites." (Wyss Study, ECF 71-11 at 703–04; Tomar Dep. at 191:8–12.) It was the "largest and most comprehensive study to date" to make these estimations. (Wyss Study at 713.) Unlike the general causation expert who "explain[ed] at length why he favors" one study over another, Dr. Busse did not even consider the Wyss study. *Wolfe v. McNeil-PPC, Inc.*, 881 F. Supp. 2d 650, 660 (E.D. Pa. 2012).

Dr. Busse's general causation opinion is also unreliable because it is based on "biological plausibility" and lacks support from epidemiological data. Biological plausibility is defined as a "judgment about whether an agent plausibly could cause a disease, based on existing knowledge about human biology and disease pathology." *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 181 (S.D.N.Y. 2009) (citing Michael D. Green et al., *Reference Guide on Epidemiology* at 388 *in* Federal Judicial Center, *Reference Manual on Scientific Evidence* (2d ed. 2000)). Biological plausibility can be important when determining general causation. *See, e.g.*, *Soldo*, 244 F. Supp. 2d at 569 (noting biological plausibility is one of the Bradford-Hill criteria used to evaluate general causation when there is a demonstrated epidemiological association).[4]

[4] While Pinkerton emphasizes these criteria, *see* (Pinkerton Mem. in Supp. of Mot. to Exclude Tomar, ECF 70-1 at 13; Pinkerton Mem. in Supp. of Mot. to Exclude Busse and Chabner, ECF 71-1

Expert testimony "should not be excluded simply because there is no literature on point" provided there are "other factors that demonstrate the reliability of the expert's methodology." *Schneider*, 320 F.3d at 406; *see Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 155 (3d Cir. 1999) (explaining a medical expert need not "always cite published studies on general causation in order to reliably conclude that a particular object caused a particular illness"). But the "best evidence of general causation in a toxic tort case" is epidemiology, and when available it "cannot be ignored." *Zoloft III*, 176 F. Supp. 3d at 492 (quoting *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 882 (10th Cir. 2005)); *see also Pritchard v. Dow Agro Scis.*, 705 F. Supp. 2d 471, 483 (W.D. Pa. 2010) (defining epidemiology as the "primary generally accepted methodology for demonstrating a causal relation between a chemical compound and a set of symptoms or a disease" (internal quotations omitted)).

Dr. Busse's belief that it is biologically plausible for smokeless tobacco products like Red Man or Skoal to cause tonsil cancer does not account for the absence of data to support general causation. He testified smokeless tobacco is held in the "back of your oral cavity, and it causes cancer" there as well as in the esophagus, so saliva containing carcinogens must "bath[e]" the tonsil given the oropharynx connects the oral cavity to the esophagus. (Busse Dep. at 123:24–124:12); *see* (*id.* at 61:2–9 (explaining part of the

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at 17–18), Plaintiffs' experts do not claim to rely on them. *Cf. Dunn v. Sandoz Pharms. Corp.*, 275 F. Supp. 2d 672, 677 (M.D.N.C. 2003) (noting the expert whose causation testimony the court excluded stated the "scientific methodology that I use to assess causation is derived from the Bradford Hill Criteria" (internal quotation omitted)). Nor would it have been appropriate to apply them here: scientists are to do so only after an epidemiological association is demonstrated. *Id.* at 678 (explaining Hill used as the "starting point" of his analysis "'an association between two variables' that is 'perfectly clear-cut and beyond what we would care to attribute to the play of chance'" (quoting Bradford Hill, *The Environment and Disease: Association or Causation*, 58 Proc. Royal Soc'y Med. 295, 295–300 (1965))). That has not happened in this case.

tonsil is below the oral cavity and "downstream" of saliva flow)). Dr. Busse said this opinion followed from anatomy and "common sense" and agreed it was based on "biological[] plausib[ility]." (*Id.* at 123:24–124:17.)

He acknowledges, however, the lack of epidemiological research establishing the necessary causal link between smokeless tobacco and tonsil cancer. Dr. Busse testified using "chewed tobacco" or "smokeless tobacco" is a risk for "head and neck cancers" but that it is "really tough" to "isolat[e]" smokeless tobacco's role in studies because "the data just aren't there." (*Id.* at 56:10–17.) He explained "teasing out" smokeless tobacco as a "unique" or "monolithic" cause of oropharyngeal cancer is "just about impossible" because smokeless tobacco consumers also tend to consume other tobacco products, like cigarettes. *See* (*id.* at 119:23–120:2, 213:23–214:11). He nonetheless estimates the risk of developing tonsil cancer from smokeless tobacco use is one and a half, compared to a baseline of one. (*Id.* at 57:3–15.) *But see Pritchard*, 705 F. Supp. 2d at 486 (noting courts that "refused to consider" epidemiological research with a relative risk less than two to support an "association between a chemical agent and a disease"). Dr. Busse separately described the risk of tonsil or oropharyngeal cancer associated with smokeless tobacco as "some glimmer" but stated it is "small." (Busse Dep. at 214:16–24.)

Expert causation testimony "generally should be supported by positive and replicated epidemiological studies." *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 466, 475 (E.D. Pa. 2014) (*Zoloft II*). When an expert's causation opinion is "equivocal or inconsistent with" epidemiological research, the expert must "thoroughly analyze" its "strengths and weaknesses." *Id.* Dr. Busse did not do so. He

attempts to reconcile his general causation opinion with existing research by pointing to the difficulty of distinguishing smokeless tobacco's role from those of confounders. But this fails to sufficiently explain why the existing research—or lack thereof—"does not contradict or undermine" his opinion. *Id.* Instead, Dr. Busse makes "speculative leaps" in claiming that a causal link exists simply because it is biologically plausible. *Id.* at 481 (explaining that not even "genuinely talented" experts can testify to "unscientific speculation"). Neither *Daubert* nor Rule 702 require the Court to admit an expert's opinion that is "connected to existing data" solely by the expert's "*ipse dixit*." *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (emphasis in original) (stating the Court is free to conclude "there is simply too great an analytical gap between the data and the opinion proffered"); *see also In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig.*, No. 18-2848, 2021 WL 5631687, at *7 (E.D. Pa. Dec. 1, 2021) (explaining *Daubert* requires "[r]eliable expert medical testimony" rather than "lay assumptions or guesswork").

Dr. Busse's opinion on general causation is also unreliable because it is not the product of a scientific methodology. Rule 702 requires his opinion to be grounded in "methods and procedures of science" instead of "subjective belief or unsupported speculation." *Paoli*, 35 F.3d at 742 (quoting *Daubert*, 509 U.S. at 590). Scientific methods are "based on generating hypotheses and testing them to see if they can be falsified." *Daubert*, 509 U.S. at 593 (internal quotation marks omitted). But it is "impossible to test a hypothesis" produced by a subjective methodology because only its "creator" can "test[] or falsify[]" it. *TMI*, 193 F.3d at 703 n.144; *see also Paoli*, 35 F.3d at 742 n.8 (listing "whether a method consists of a testable hypothesis" as one of the

eight factors the Third Circuit has adopted for assessing reliability); *cf. Soldo*, 244 F. Supp. 2d at 451, 533 (noting epidemiology is "by its very nature 'testable,'" because it has "methods and standards" and that its "very purpose" is serving the "type of testing function required by *Daubert*").

Dr. Busse implies one reason a causal relationship between smokeless tobacco products and tonsil cancer has not been established is the difficulty of "teasing out" smokeless tobacco's role. (Busse Dep. at 119:23–120:4.) So understood, his view that Red Man or Skoal can cause tonsil cancer is not reliable because it is nothing more than an "untested hypothesis." *Zoloft II*, 26 F. Supp. 3d at 473; *cf. Zoloft III*, 176 F. Supp. 3d at 495 (explaining a proposed expert's statement of "reasons why a particular study may not have found a positive association" "falls far short of establishing causation"). Alternatively, Dr. Busse's view is not scientific because it is "mere subjective belief" propped up by biological plausibility rather than an "objective inference[] from the relevant scientific evidence"—which does not draw the necessary causal connection between Defendants' smokeless tobacco products and tonsil cancer. *Soldo*, 244 F. Supp. 2d at 504–05. Decisions "based on less than sufficient and/or reliable scientific evidence" are "guesses" that "do not constitute a scientifically reliable approach" for evaluating causation. *Id.* at 505.

2

Dr. Busse's general causation opinion also does not fit the facts of this case. There are many smokeless tobacco product types, and they carry different risks. (Pinkerton SOMF ¶ 36); *see also* (Murrelle Rpt., ECF 71-7 at 21, 23 (presenting "risk continuum" graph and photos of smokeless tobacco products used worldwide)). Yet Dr.

Busse's general causation opinion is "independent of" Skoal or Red Man. (Busse Dep. at 71:8–13.) In developing it, he did not separate moist snuff (Skoal) from loose leaf chewing tobacco (Red Man). (*Id.* at 180:21–181:2.) The result is an opinion that will not "help the trier of fact to understand the evidence or to determine a fact in issue" or constitute "scientific knowledge *for purposes of the case*." Fed. R. Evid. 702(a); *Paoli*, 35 F.3d at 743 (emphasis in original); *cf. Soldo*, 244 F. Supp. 2d at 548 (explaining evidence about the "effect of allegedly 'similar' [products] on the body" does not fit because it is no "substitute for direct evidence about the [product] in question").

For example, the Surgeon General report differentiated snuff from "chewing tobacco" and noted evidence the latter can increase oral cancer risk is "not so strong" and the "risks have yet to be quantified." (ECF 71-2 at ¶ 3.) Additionally, the 1981 article focused on snuff products—not loose leaf chewing tobacco. *See* (Winn Art.). The relevant questions are whether Skoal moist snuff or Red Man loose leaf chewing tobacco can cause tonsil cancer, but Dr. Busse's general causation opinion is not calibrated to the cancer risks posed by those particular products. His opinion is not "sufficiently tied to the facts of the case" to "aid the jury." *Daubert*, 509 U.S. at 591 (internal quotation omitted).

C

1

Dr. Chabner's general causation opinion is not reliable either. In his report, he states there is "undeniable" evidence—recognized by international and national health organizations—that "smokeless tobacco products cause human cancer." (Chabner Rpt., ECF 71-6 at 3.) He cites IARC's determination that smokeless tobacco is "carcinogenic

to humans" and causes "oral cavity" cancers and the Surgeon General's conclusion that "smokeless tobacco can cause cancer and other non-cancerous oral conditions and can lead to nicotine addiction and dependence." (*Id.*) He writes that, according to the CDC and AAO, smokeless tobacco contains "cancer causing [TSNAs] and multiple other substances identified as carcinogens." (*Id.*) Finally, he asserts "[i]t has been determined" that smokeless tobacco users "experience greater than 10 fold increases in the risk of cancers of the mouth, gums, oropharynx, larynx, and salivary glands as compared to non-users of tobacco products," and for these anatomical sites the cancer risk is equal to that experienced by a smoker "of up to 20 cigarettes a day." (*Id.* at 3–4.)

Like Dr. Busse, Dr. Chabner did not adequately consider the relevant literature. *See Zoloft I*, 26 F. Supp. 3d at 460–61. Dr. Chabner also erroneously relied on the IARC and 1986 Surgeon General report. Further, a significant part of his "literature review" consisted of background reading in medical textbooks; in his expert report he cited to one paper, which he learned about from Hoefling's lawyer. *See* (Chabner Dep. at 163:23–164:15, 165:8–11, 165:18–166:8). At his deposition, he clarified that the finding cited in his report that smokeless tobacco use multiplies by more than ten the oropharyngeal cancer risk actually applies only to mouth and gum cancers. (*Id.* at 182:15–184:13.) Relying on a "selected subset of evidence without sufficient analysis of contrary evidence" is a "significant methodological weakness." *Zoloft I*, 26 F. Supp. 3d at 461 (noting "'[c]herry-picking' is always a concern").

Dr. Chabner's general causation opinion also unduly relies on biological plausibility. Noting the IARC's conclusion that smokeless tobacco is carcinogenic for head, neck, esophageal and pancreatic cancers, Dr. Chabner explains "there's a lot of

structures on the way down that had to be exposed to the same material coming from the smokeless tobacco." (Chabner Dep. at 81:23–82:4.) Dr. Chabner "assume[s] that the pharynx is exposed." (*Id.* at 171:5–17.) He points to "general knowledge of people in my field that [smokeless tobacco] causes *oral cancer*." (*Id.* at 179:9–18 (emphasis added).) The "supporting assumption[s]" for Dr. Chabner's general causation theory are not "sufficiently grounded in sound" reasoning and methodology to enable it "to clear the reliability hurdle." *TMI*, 193 F.3d at 677 (explaining "[a]ssumption-based conclusions" that fail this test "can hardly be relied upon as 'good science'"). More fundamentally, there is a dearth of research to support it. *See Zoloft II*, 26 F. Supp. 3d at 475. Even if Dr. Chabner's series of inferences is sensible according to biological principles, expert testimony is inadmissible under *Daubert* if "any step" in the expert's analysis makes it unreliable. *Paoli*, 35 F.3d at 745. That is true here for multiple steps. Dr. Chabner's reasoning and methodology are not "sufficiently reliable to allow" the jury to consider his opinions. *TMI*, 193 F.3d at 665.

Dr. Chabner acknowledges an absence of data to support the view that Red Man or Skoal can cause tonsil cancer in general. He notes tonsil cancer is "very rare." (Chabner Dep. at 125:20–23.) Based on his review of epidemiological research, the number of cases is "much too small" to determine whether smokeless tobacco causes tonsil cancer—and the "clearest" data are available for oral cancer. (*Id.* at 81:13–16, 125:4–19); *see* (*id.* at 84:6–7, 84:16–20 (explaining there are a "number of deficiencies or lack of data" identifying a causative link between smokeless tobacco and oropharyngeal cancer and noting the relevant research contains "surprisingly scanty" patient numbers)). It would require a "whole different level of approach to this issue to

determine whether the nonsmoking, non-HPV cancers of the tonsils are related to smokeless tobacco." (*Id.* at 84:7–10.)

Indeed, in an effort to explain just how weak the epidemiological evidence was, Dr. Chabner compared the evidence linking smokeless tobacco products to oropharyngeal cancer to an earlier study that found an association between insulin and cancer. (Chabner Dep. at 86:6–87:9.) Both involved "small numbers of patients and incomplete data" that were "just not sufficient to draw conclusions about carcinogenesis." (*Id.* at 86:23 –87:3.) He explained that without "a totally different kind of study," it was "really impossible to draw any conclusions." (*Id.* at 89:19–21.) His own experience cautions against drawing causal conclusions in the face of inconclusive epidemiological research: when a more robust study reexamined the link between insulin and cancer, it demonstrated no causal association existed. (*Id.* at 21–24.) Ultimately, he agrees with U.S. Smokeless' epidemiologist that the available data does not support the conclusion that smokeless tobacco causes tonsil cancer. (*Id.* at 90:2–10, 174:13–14.)

This absence of supporting data renders unreliable Dr. Chabner's view that Red Man and Skoal can cause tonsil cancer in general. *See Schneider*, 320 F.3d at 404. It does not "reliably follow from the facts known to [Dr. Chabner] and the methodology [he] used." *Heller*, 167 F.3d at 153. Dr. Chabner's general causation opinion also lacks a scientific foundation for largely the same reasons as Dr. Busse's. *See Paoli*, 35 F.3d at 742 (explaining that Daubert's reliability prong requires determining the "scientific validity" of scientific evidence).

2

Moreover, Dr. Chabner's general causation opinion does not fit the case. His report does not distinguish between types of smokeless tobacco. *See* (ECF 71-6 at 3–4). He concedes he is "not an expert" on smokeless tobacco-product details but acknowledges "the products are different." (Chabner Dep. at 91:3–9.) It is "really hard to say, in a blanket way, that smokeless tobacco is all the same and that we can do a study that way." (*Id.* at 91:12–14.) Nonetheless, he did not consider the 1986 Surgeon General report's statement differentiating chewing tobacco from moist snuff. (*Id.* at 178:22–179:8.)

Dr. Chabner's opinion lacks "good grounds" given his failure to grapple with the differences between smokeless tobacco product types. *Paoli*, 35 F.3d at 743 (explaining *Daubert*'s "good grounds" standard applies to the part of an expert's analysis that "connects the work of the expert to the particular case"); *e.g.*, *Zoloft I*, 26 F. Supp. 3d at 458–60 (rejecting the argument that it is proper for an expert to interpret data about a class of drugs to support the existence of a causal relationship between a drug in that class and birth defects).

D

1

Dr. Tomar's general causation opinion also does not fit the case. First, he opines using "moist snuff or loose leaf chewing tobacco" causes "cancer in humans." (Tomar Rpt., ECF 70-3 at 5.) Dr. Tomar explained he reached this conclusion following "extensive reviews of the scientific evidence conducted by expert panels convened by" the Surgeon General and IARC. (*Id.* at 6.) Second, he maintains Skoal and Red Man

contain "high levels of substances established as carcinogenic to humans." (*Id.* at 5.) Dr. Tomar notes CDC and FDA analyses found "relatively high levels of TSNAs" in Skoal and Red Man. (*Id.* at 6.) Third, he explains that while TSNA levels in Skoal "may have declined" in the 1980s, they have stayed "very high" compared to other types of smokeless tobacco and "changed little since at least the early 1990s"; and Red Man's TSNA levels "have not changed appreciably" dating to "at least the 1980s." (*Id.* at 5.) Dr. Tomar explains early-1990s published research suggested levels of two TSNAs, NNN and NNK, in leading U.S. moist snuff brands had declined since 1980 but a 2004 measure of those levels "suggests that nearly all varieties and flavors of [Skoal] had TSNA levels that were as high as or higher than had been reported a decade earlier." (*Id.* at 6–7.) Dr. Tomar notes that in 2009 NNN and NNK levels "remained much higher in Skoal products than in other Altria-manufactured smokeless tobacco products." (*Id.* at 7.) He also explains that while Red Man's TSNA levels are "lower than those reported" for Skoal, they have not "changed appreciably since at least the early 1980s" and have stayed "much higher than levels found in low-TSNA smokeless tobacco products." (*Id.*)

Dr. Tomar's report includes generic opinions about smokeless tobacco's carcinogenicity and TSNA content rather than an opinion directly applicable to the relevant question: whether Red Man and Skoal can cause tonsil cancer. *See Schneider*, 320 F.3d at 404 (describing Rule 702's fit requirement). His report's first opinion—using "moist snuff or loose leaf chewing tobacco" causes "cancer in humans"—is too broad to help the jury. (Tomar Rpt. at 5); *Daubert*, 509 U.S. at 591–92. It makes no difference that Dr. Tomar based this conclusion on "extensive reviews" by experts

because it lacks a "valid scientific connection to the pertinent inquiry" on general causation. (Tomar Rpt. at 6); *Daubert*, 509 U.S. at 591–92. The same goes for his opinions about TSNAs. Although they may be logically relevant in the evidentiary sense, they lack a specific connection to general causation here. *See Paoli*, 35 F.3d at 745 (stating the fit standard is "higher than bare relevance"); Fed. R. Evid. 401.

A different example underscores why Dr. Tomar's general causation opinions would not "assist the trier of fact." *Schneider*, 320 F.3d at 404. He stated the 2016 Wyss study's "bottom-line conclusion" was consistent with the proposition that "the use of smokeless tobacco [is] a carcinogen." (Tomar Dep. at 200:11–14.) Even if true, it is only a small part of the picture. As Pinkerton expert Walter Lee noted, carcinogen exposure "by itself is not a guarantee of cancer formation." (Lee Rpt., ECF 82-5 at 2.)

2

Dr. Tomar's opinion on general causation is also unreliable. In connecting his generic opinions about the carcinogenicity of smokeless tobacco to tonsil cancer in particular, he resorts to biological plausibility, following the errant path taken by Drs. Busse and Chabner. He claims smokeless tobacco products have not been "established" as safe and that they "continue to have relatively high levels of known carcinogens," among them TSNAs—which "certainly would be consistent with there being an elevated risk" for tonsil cancer. (Tomar Dep. at 138:15–24.) He contends it is "hard to imagine a mechanism" through which there is an increased esophageal cancer risk from smokeless tobacco "without the carcinogens contacting the oropharynx." (*Id.* at 185:20–23); *see also* (*id.* at 263:18–264:1 (explaining smokeless tobacco products are known carcinogens and "[b]iologically" it "wouldn't make sense" for the cancer risk to "stop[]

right at the opening of the pharynx")).

Dr. Tomar appears to have conducted a more thorough literature search than Drs. Busse and Chabner. *See* (Tomar Dep. at 101:20–23, 105:3–10, 106:11–16). But like his colleagues, he ultimately could not move past biological plausibility and identify data to support general causation. This failure was not due to neglect: Dr. Tomar admits that when a theory is biologically plausible, it requires support from epidemiological research. (*Id.* at 192:23–193:1.) He agrees a biological plausibility-based theory of general causation like his ordinarily "would be supported by" an investigation into particular anatomical sites, like the oropharynx, to identify supporting evidence. *See* (*id.* at 185:25–186:13).

Yet the existing research falls short. A general causation expert must address "both supportive and contrary evidence" when forming an opinion. *Zoloft II*, 26 F. Supp. 3d at 470 (explaining the impermissibility of ignoring "findings of those studies from which conclusions at odds with [the expert's] opinion were drawn"). A commentary on a 2002 article Dr. Tomar co-authored, while noting the article's limitations, stated "[i]nterestingly, chewing tobacco and moist tobacco were not associated with an increased cancer risk of the oral cavity, the *oropharyngeal cavity*, or the larynx." (ECF 70-5 at 226 (emphasis added).) Dr. Tomar also reviewed the 2016 Wyss study, which he describes as the most "on point" for his work on this case, noting that "really small sample sizes" could make it difficult to draw meaningful conclusions from "site-specific estimates." *See* (Tomar Dep. at 188:7–12, 199:7–9, 201:4–6); (*id.* at 264:2–5 (stating there is no "precise" estimate "specific to the tonsil" for the cancer risk of using smokeless tobacco products)). Notwithstanding this absence of data, Dr.

Tomar estimates using smokeless tobacco at least "doubl[es]" oropharyngeal cancer risk. (*Id.* at 264:21–265:5.) He came to this guess by analogizing to the oral cavity. (*Id.* at 265:17–266:4.)

The biological plausibility and analogical reasoning Dr. Tomar used to form his view that Skoal or Red Man can cause tonsil cancer are not scientific "principles and methodology" that open the *Daubert* gate. 509 U.S. at 595. Rather, they amount to "subjective belief or unsupported speculation." *Id.* at 590. His view is not "based on valid reasoning and reliable methodology." *TMI*, 193 F.3d at 665 (internal quotation marks omitted). Moreover, Dr. Tomar's methods fail at least three of the Third Circuit's reliability factors. *Paoli*, 35 F.3d at 742 n.8. They amount to an "[un]test[ed]" hypothesis (or, alternatively, one not validated in the limited testing that has been done); there are no "standards controlling [their] operation"; and they bear precisely the wrong type of "relationship" to the most important "method[] which ha[s] been established to be reliable": they are unmoored from epidemiological data. *Id.*; *see Zoloft II*, 26 F. Supp. 3d at 475.

E

Even if Hoefling's experts had reliably established general causation, the Court would exclude Drs. Busse's and Chabner's specific causation opinions. While both doctors purport to reach their conclusions based on a differential etiology of Hoefling's tonsil cancer, (Busse Rpt. at 4; Chabner Dep. at 202:7), neither could rule out HPV as the cancer's cause, and they lack "good grounds" for believing smokeless tobacco use was the more likely cause. *Daubert*, 509 U.S. at 590.

Physicians may base their opinions on the cause of a person's illness on a

properly performed differential etiology.[5] *See Heller*, 167 F.3d at 154. When conducting such an analysis, the expert must "rule in" then "rule out" possible causes of the illness. *Zoloft III*, 176 F. Supp. 3d at 494. Experts are not required to address all possible causes, but "[o]bvious alternative causes need to be ruled out." *Heller*, 167 F.3d at 156 (quoting Daniel J. Capra, *The* Daubert *Puzzle*, 32 Ga. L. Rev. 699, 728 (1998)).

Once a defendant points to a plausible alternative cause of the plaintiff's illness, the expert must "offer a good explanation as to why his or her conclusion remains reliable." *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 808 (3d Cir. 1997). A physician need not perform every possible test to confirm his opinion, but he must "employ[] sufficient diagnostic techniques to have good grounds" for his conclusion. *Paoli*, 35 F.3d at 761.

1

The first problem with Drs. Busse's and Chabner's differential etiologies is that they resisted "ruling in" tonsil cancer's predominant cause: HPV. HPV accounts for eighty percent of tonsil cancers. (Pinkerton SOMF ¶ 92.) Despite this statistic, both experts demanded affirmative evidence that Hoefling had an HPV infection before meaningfully considering it as a possible cause.

In his report, Dr. Busse explains he could not "rule . . . in" HPV without a positive P-16 test.[6] (Busse Rpt. at 4.) Dr. Chabner said he dismissed HPV as a

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[5] While this method is often referred to as "differential diagnosis," differential etiology is the more precise term. A differential diagnosis is used to determine what condition a patient has; a differential etiology is used to deduce its cause. *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1194 n.5 (11th Cir. 2010).

[6] P-16 is a protein associated with HPV-related cancers. (Busse Dep. at 61:16–20.)

possible cause because there was no "overwhelming evidence" Hoefling had the virus. (Chabner Dep. at 174:19–22.) Nothing short of "a wife with cervical cancer" or "a positive P-16" test would have led him to consider HPV as a cause. (*Id.* at 174:24–175:1.) This approach is flawed given both HPV's pervasiveness and the low probability it would have been detected before Hoefling's cancer diagnosis. As Dr. Busse explained, most men with HPV infections in the throat "would never know" they were infected. (Busse Dep. at 135:17–136:2.)

A proper differential etiology does not work like this. Differential etiology is a reliable technique because it requires doctors to demonstrate, through a process of elimination, that their hypothesized cause is more likely than alternative causes. *Paoli*, 35 F.3d at 758; *Feit v. Great W. Life & Annuity Ins. Co.*, 271 F. App'x 246, 254 (3d Cir. 2008). The absence of a positive HPV test is not evidence HPV was absent. *Soldo*, 244 F. Supp. 2d at 521. It was improper to treat HPV as implausible simply because no conclusive test was performed. Doing so spared Drs. Busse and Chabner's preferred hypothesis from "the rigors of scientific testing," *Paoli*, 35 F.3d at 764, and undermined the reliability of their differential etiologies.

Indeed, while Dr. Chabner claims to have performed a differential etiology, the process he describes does not involve methodically ruling out alternative causes. He "just came to the conclusion" that smokeless tobacco contributed to Hoefling's cancer after looking at what he considered the relevant risk factors. (Chabner Dep. at 202:10–19.) In doing so, he emphasized "there's no cookbook that can tell you exactly how to weigh [those factors] in individual patients." (*Id.* at 202:9–10.) While this holistic approach may be useful in medical practice, it is not a rigorous method for proving

causation. *See In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 858 F.3d 787, 797 n.52 (3d Cir. 2017) ("[A] scientific method of weighting must be explained to prevent a 'conclusion-oriented selection process.'") (quoting *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 607 (D.N.J. 2002)).

2

The second problem with Drs. Busse's and Chabner's differential etiologies is that if HPV had been ruled in, it could not be reliably ruled out without a successful tumor biopsy. Both experts acknowledge a tumor biopsy could have determined whether Hoefling's cancer was HPV related. *See* (Busse Dep. at 62:4–5 ("the definitive tests . . . would have been of the tonsil tissue itself.")); (Chabner Dep. at 197:23–198:4, 204:4–205:5). But the fine needle biopsy of Hoefling's tumor was indeterminate, and his treating physician did not order additional testing. (Pinkerton SOMF ¶¶ 20–21.)

Given the difficulty of detecting HPV and the fact that it is the leading cause of tonsil cancer, Drs. Busse and Chabner could not rule out HPV without this test. Busse admits that without more testing, "we really don't know if there was HPV or not." (Busse Dep. at 61:22–24); *see also* (*id.* at 162:15–163:10). In his mind, there is "an equal probability" that HPV or smokeless tobacco caused the cancer, but "unfortunately there's no way to know." (*Id.* at 173:13–15.) Similarly, Dr. Chabner agrees "HPV is still one of those things that's out there that we cannot rule out." (Chabner Dep. at 204:24–205:5); *see also* (*id.* at 136:20 ("HPV could be the cause. We don't know.")).

As their concessions show, neither Busse nor Chabner dispute that a tissue biopsy is necessary to properly rule out HPV. In his own practice, Dr. Busse would have conducted some sort of biopsy to determine whether the cancer was HPV related.

(Busse Dep. at 62:4–9, 63:10–64:7.) Without one, any differential etiology will be inconclusive. (*Id.* at 62:11–12 ("[T]he fact is we have two . . . possible causes for why he developed cancer.").) Dr. Chabner agrees it is important to test tonsil cancers for HPV whenever possible. (Chabner Dep. at 48:9–49:5, ECF 76-12). To the extent Hoefling's experts defend the decision not to attempt another biopsy, they do so on pragmatic grounds: Hoefling's physician may have foregone further testing because Hoefling's *treatment* would have been the same regardless of his cancer's cause. (Busse Dep. at 67:22–68:6, ECF 76-8; Chabner Dep. at 204:15–23, ECF 71-4.) That may be true, but it does not diminish the importance of a biopsy for determining the *cause* of his cancer.

3

In the absence of a conclusive tissue biopsy, Drs. Busse and Chabner turned to other heuristics to discount, if not rule out, HPV as a cause of Hoefling's cancer. Because the standard method for ruling out HPV—a biopsy—was indeterminate, the experts needed to demonstrate that the alternative grounds for their conclusions were reliable. *See Zoloft*, 858 F.3d at 797 ("[S]tandard techniques bolster the inference of reliability; nonstandard techniques need to be well-explained."). They failed to do so. None of the reasons they offer for rejecting HPV—Hoefling's age, his sexual history, the opinion of his treating physician, the absence of an HPV diagnosis in his and his wife's medical records and his long history of smokeless tobacco use—were "good grounds" for ruling out the most frequent (by far) cause of tonsil cancer.

First, both physicians argue HPV was unlikely to be the cause of Hoefling's cancer because of his age. (Busse Dep. at 61:24–62:2, ECF 71-3; Chabner Rpt. at 4, ECF 71-6.) They point out HPV accounts for a higher proportion of oropharyngeal

cancers among younger people. (Busse Dep. at 134:11–14.; Chabner Rpt. at 4). But HPV accounting for a higher proportion of oropharyngeal cancer cases among younger people does not make it less likely to cause cancer in older people. It may be that other risk factors, like alcohol use or smoking, are less likely to cause tonsil cancer in younger patients, and that the incidence of HPV-related cancers is relatively constant. Indeed, one recent study found more than sixty-five percent of oropharyngeal cancers in those age seventy and over were HPV-positive. (Steinau Study at 824, ECF 71-13.)

When confronted with this data, Dr. Busse acknowledged HPV could not be ruled out based on Hoefling's age. (Busse Dep. at 162:11–14, 156:23–157:6.) Dr. Chabner similarly conceded that it has "never been a contention" that HPV does not cause oropharyngeal cancer in older people. (Chabner Dep. at 136:12–13.) He speculates that the incidence of HPV might be lower among eighty-year-olds than it was among seventy-year-olds, (*id.* at 136:18–24), but offers no supporting evidence. He merely suggests that because the rate of HPV-positive cancers was lower among those older than seventy than it was in younger cohorts, further disaggregated data might show the rate continues to decline at higher ages. But the seventy-plus HPV-positive cohort in the Steinau study ranged from seventy to nintety-two and the study contained no additional information about age distribution within the cohort that might support Dr. Chabner's guess. (Steinau Study at 824.) Ultimately, neither expert cites evidence for why age was a "good ground" for ruling out HPV, and the Court is not required to take their word for it. *Zoloft III*, 176 F. Supp. 3d at 495.

Second, Drs. Busse and Chabner cite Hoefling's sexual history as a reason to rule out HPV. Dr. Busse contends that Hoefling's "serial monogamy" put him at lower risk

of HPV, (Busse Dep. at 61:24–62:4), while Dr. Chabner believes that because Hoefling never had oral sex, HPV was unlikely to have caused his cancer, (Chabner Dep. at 136:15–16.).

Record evidence, however, undercuts Busse and Chabner's reasoning. In addition to his four wives, Hoefling "had girlfriends" during the 1970s. (Hoefling Dep. at 110:6). While he considers only two of his non-marital relationships "significant," (*id.* 107:3–112:16), they were two among "many," (*id.* at 112:7). During his deposition, Dr. Busse acknowledged that if Hoefling had not been monogamous in his middle age, he would be at higher risk for HPV infection. (Busse Dep. at 197:12–17.) Even if Dr. Busse had pointed to studies showing that serial monogamy decreased the risk of HPV infection, which he did not, there is no basis for concluding that Hoefling had in fact been "serially monogamous."

Dr. Chabner's opinion is also unmoored from reality. He admits he never asked Hoefling whether he engaged in oral sex. (Chabner Dep. at 80:1–3.) He "got the impression" he had never had oral sex from his lawyer. (*Id.* at 80:12–16). As the Third Circuit explained in *In re Paoli Railroad Yard PCB Litigation*, "a physician who evaluates a patient in preparation for litigation should seek more than a patient's self-report of symptoms or illness." 35 F.3d at 762. Dr. Chabner did even less, basing a critical part of his analysis on nothing more than the assertions of plaintiffs' counsel.

More to the point, both experts agree HPV is prevalent and easily acquired. *See* (Busse Dep. at 218:7–10 (agreeing HPV is a "ubiquitous virus that most people contract")); (Chabner deposition 144:24–145:19 (explaining "there are a lot of ways of getting HPV" and "most people" have been exposed to HPV without knowing it)). And

neither cite research to support their conclusion that Hoefling's lifestyle put him at particularly low HPV risk. Indeed, Dr. Chabner admits he is merely speculating. (Chabner Dep. at 145:14–16 ("I don't know. I'm not a sexual epidemiologist.").) An expert cannot eliminate alternative causes based on "subjective beliefs or unsupported speculation." *Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1058 (9th Cir. 2003) (citation omitted).

Third, both experts rely on the opinion of Hoefling's treating oncologist, who "doubted" HPV had caused his tonsil cancer, but did not explain why. (Busse Rpt. at 4; Chabner Rpt. at 4.) Faith in the wisdom of treating physicians "is not the stuff of science." *C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 837 (7th Cir. 2015). Drs. Busse and Chabner offer no explanation for why they believe his doubt is reliable. They cannot rest on the *ipse dixit* of Hoefling's physician any more than they can on their own.

Fourth, Drs. Busse and Chabner suggest in their reports that HPV was less likely because neither Hoefling nor his wife had a reported history of HPV. (Busse Rpt. at 4, Chabner Rpt. at 4) But Dr. Busse explained HPV is unlikely to show up in a man's medical records. (Busse Dep. at 165:2–13, ECF 76-8.) And Margaret Hoefling's lack of a reported history of HPV could be because the appropriate testing was never performed or the virus was dormant, rather than because she and her husband did not have it. *See* (Busse Dep. at 165:19–167:4). There is no evidence either expert reviewed her complete medical records, *cf. Paoli*, 35 F.3d at 762, let alone that those records would support the conclusion that if Gus Hoefling had HPV, it would be evident from Margaret Hoefling's medical history. Busse and Chabner cannot simply assume Mrs.

Hoefling's doctors would have detected HPV had it existed. *See C.W.*, 807 F.3d at 837; *Soldo*, 244 F. Supp. at 521.

Fifth, to the extent either expert falls back on Hoefling's long history of using smokeless tobacco as a justification for ruling out HPV, their reasoning is "fatally circular." *Soldo*, 244 F. Supp. 2d at 519. Differential etiology would have no power to test a hypothesis if the allure of the hypothesis itself could justify ruling out obvious alternative explanations.

For their differential etiologies to be reliable, experts must use scientifically valid methodologies to rule out plausible alternative causes. *Zoloft III* at 495; *see also Kannankeril*, 128 F.3d at 808. Drs. Busse and Chabner did not. In the absence of a successful tissue biopsy, the only reliable means for determining whether HPV caused the cancer, they offer guesses about the probability of an HPV infection that are unsupported by science, the record, or both. Both experts admit they cannot actually rule out HPV. (Busse Dep. 173:13–15; Chabner Dep. 204:24–205:5.) Even if smokeless tobacco were as likely as HPV to have caused Hoefling's cancer, their inconclusive differential etiology would not support the conclusion that tobacco was the more likely cause.[7] (Busse Dep. at 62:20–63:1; Chabner Dep at 137:18–21). There is too great a

[7] Drs. Busse's and Chabner's reports cursorily suggest that even if smokeless tobacco was not "the" cause of Hoefling's cancer, it was "a" significant contributing factor. (Busse Rpt. at 4; Chabner Rpt. at 4). This alternative theory, which was not explained in their reports or during their depositions, does not diminish the importance of a proper differential etiology. If Hoefling is proceeding on a theory of concurrent causation, he still needs expert testimony to show smokeless tobacco played *some* role in causing his cancer. *See Rost v. Ford Motor Co.*, 151 A.3d 1032, 1050 (Pa. 2016). Hoefling's experts provide no basis for an opinion that smokeless tobacco can contribute to an HPV-related cancer. Both agree HPV can cause tonsil cancer on its own. *See* (Chabner Dep. at 199:18–19 ("We know that [HPV] causes this cancer by itself.")); (Busse Dep. 65:22 –24). Dr. Busse believes HPV is a "separate causal pathway" for tonsil cancer and, if it were the cause of Hoefling's cancer, it would be "the overriding determinant" of the outcome. (Busse Dep. 65:3–24; 29:22–30:2.) While Dr. Chabner holds out the possibility that smokeless tobacco could contribute to an HPV-

gap between their analysis and that conclusion. *See Joiner*, 522 U.S. at 146.

III

Pinkerton and U.S. Smokeless are entitled to summary judgment for two reasons. First, Hoefling has not produced admissible expert testimony on the issue of causation, a necessary element of his claims. Second, even if his experts' causation opinions were allowed, these opinions are inadequate to establish a jury question on medical causation under Pennsylvania law.

A

Summary judgment is proper if the movant proves there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. Fed R. Civ. P. 56(a). A fact is "material" if it may affect the outcome of the suit under the governing law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A "genuine dispute" exists "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* A mere scintilla of evidence supporting the nonmoving party, however, will not suffice. *Id.* at 252. Rather, the nonmovant must "set forth specific facts showing that there is a genuine issue for trial." *Id*. at 256.

At summary judgment, a court may consider any material in the record that may be admissible at trial. *See* Fed. R. Civ. P. 56(c); *Pamintuan v. Nanticoke Mem'l Hosp.*, 192 F.3d 378, 387–88 & n.13 (3d Cir. 1999). In doing so, a court "must view the facts in the light most favorable to the nonmoving party and draw all inferences in that party's favor." *Prowel v. Wise Bus. Forms*, 579 F.3d 285, 286 (3d Cir. 2009). But it need not

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related cancer, he cannot even guess about what role it would play. (Chabner Dep. at 197:23–198:24.) He merely remains "suspicious" that smokeless tobacco would be a contributing factor.

credit "[u]nsupported assertions, conclusory allegations, or mere suspicions." *Betts v. New Castle Youth Dev. Ctr.*, 621 F.3d 249, 252 (3d Cir. 2010). Nor may a court make credibility determinations or weigh the evidence. *See Parkell v. Danberg*, 833 F.3d 313, 323 (3d Cir. 2016).

To succeed on any of his claims, Hoefling must prove the Defendants' products caused his cancer. *See Mellon v. Barre-Nat'l Drug Co.*, 636 A.2d 187, 191 (Pa. Super Ct. 1993) ("Proof of causation is a necessary element in a products liability action as well as in a negligence action."). Expert testimony is generally required to prove causation of a medical condition. *Feit v. Great W. Life & Annuity Ins. Co.*, 271 F. App'x 246, 252 (3d Cir. 2008); *see also Cohen v. Albert Einstein Med. Ctr.*, 592 A.2d 720, 723 (Pa. Super Ct. 1991) (explaining that expert testimony is necessary where the case's facts are beyond an ordinary layperson's knowledge). Because Drs. Busse's, Chabner's and Tomar's expert opinions are inadmissible, no genuine issues of fact with respect to causation remain for the jury. *See Paoli*, 35 F.3d at 785.

B

Pinkerton and U.S. Smokeless would be entitled to summary judgment even if Hoefling's experts' causation opinions were admitted. Under Pennsylvania law, experts on medical causation must testify to "a reasonable degree of medical certainty." *Paoli*, 35 F.3d at 750. This is not merely an evidentiary requirement; it forms part of the plaintiff's burden of proof. *Id.* at 751. If a plaintiff lacks evidence to satisfy this standard, summary judgment is appropriate. *Id.* at 752; *see also Valido-Shade v. Wyeth LLC*, 57 F. Supp. 3d 457, 461 (E.D. Pa. 2014); *Eaddy v. Hamaty*, 694 A.2d 639, 642–43 (Pa. Super. Ct. 1997).

Whether an expert satisfies this standard does not depend on "magic words." *Commonwealth v. Spotz*, 756 A.2d 1139, 1160 (Pa. Super. Ct. 2000). Instead, the Court determines whether the expert's testimony, taken as a whole, is based on "a reasonable degree of medical certainty rather than upon mere speculation." *Vicari v. Spiegel*, 936 A.2d 503, 510 (Pa. Super. Ct. 2007) (quoting *Spotz*, 756 A.2d at 1160). Pennsylvania courts have long drawn a distinction between reasonable certainty and probabilistic guesswork. *See id.* at 511; *Kravinsky v. Glover*, 396 A.2d 1349, 1356 (Pa. Super. Ct. 1979). Testimony that something was "more likely than not" the cause of the plaintiff's injury is insufficient. *Griffin v. Univ. of Pittsburgh Med. Ctr.–Braddock Hosp.*, 950 A.2d 996, 1003 (Pa. Super. Ct. 2008). Similarly, an expert does not express the requisite certainty when he puts the odds in favor of his theory of causation at just above fifty-fifty. *See id*; *Valido-Shade*, 57 F. Supp. 3d at 461.

Dr. Busse's testimony clearly falls below this threshold. He believes there is "an equal probability" that either smokeless tobacco or HPV caused Hoefling's cancer. (Busse Dep. at 173:13–15); *see also* (*id.* at 62:20–63:1). Indeed, he cannot say either was *likely* the cause of Hoefling's cancer. (*Id.* at 172:9–12 (explaining "you really almost can't speculate" about the most likely cause of Hoefling's cancer)); *see also* (*id.* at 225:22–226:8 ("[I]t's like you have . . . six candidates on an election slate. You could win with twenty-one percent.")).

Dr. Chabner's testimony is similarly inadequate. At deposition, he continuously expressed his opinion on causation in terms of probability hovering near fifty percent. (Chabner Dep. 188:8–10, ECF 173-4 ("[I]f I had to put a percentage on it, greater to fifty percent chance that [smokeless tobacco] was a significant factor")); (*id.* at 202:19–20

("[T]he chances were greater than yes and no.")); (*id.* at 137:18–21 (arguing the Steinau study suggested "at least a fifty-fifty chance, if not better, that it's not HPV related")). A reasonable degree of medical certainty requires more than a finding by a preponderance of the evidence. *See Griffin*, 950 A.2d at 1004 n.5. Dr. Chabner's testimony closely tracks the more likely than not, fifty-one-to-forty-nine odds that courts have found insufficient to meet that higher standard. *Id.* at 1003–04, *Valido-Shade*, 57 F. Supp. 3d at 461.

V

Because Gus Hoefling's negligence and strict liability claims against Pinkerton and U.S. Smokeless cannot survive summary judgment, the Court also grants summary judgment on Margaret Hoefling's loss of consortium claim. The viability of her claim depends on those of her husband. *See Marshall v. Zimmer, Inc.,* No. 18-3363, 2020 WL 5408209, at *9 (E.D. Pa. Sept. 9, 2020).

An appropriate Order follows.

BY THE COURT:

/s/ Gerald J. Pappert
GERALD J. PAPPERT, J.